

.....
(Original Signature of Member)

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food and Drug Import Safety Act of 2007”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

- Sec. 2. Research on testing techniques for use in inspections of imported food safety; priority regarding detection of intentional adulteration.
- Sec. 3. User fees regarding inspections of imported food safety.
- Sec. 4. User fees regarding inspections of imported drug safety.
- Sec. 5. Authority to restrict food importation to specific ports of entry.
- Sec. 6. Country of origin labeling.
- Sec. 7. Safe and secure food importation program.
- Sec. 8. Civil penalties.
- Sec. 9. Continued operation of field laboratories.
- Sec. 10. Recall authority.
- Sec. 11. Inspection and other standards; applicability, enforcement; certifications.
- Sec. 12. Regulations on adequate testing of processed food.
- Sec. 13. Records of interstate shipment.
- Sec. 14. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.

1 **SEC. 2. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
2 **INSPECTIONS OF IMPORTED FOOD SAFETY;**
3 **PRIORITY REGARDING DETECTION OF INTEN-**
4 **TIONAL ADULTERATION.**

5 Section 801 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 381) is amended by adding at the end the
7 following:

8 “(p) RESEARCH ON TESTING TECHNIQUES FOR USE
9 IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

10 “(1) IN GENERAL.—The Secretary shall (di-
11 rectly or through grants or contracts) provide for re-
12 search on the development of tests and sampling
13 methodologies, for use in inspections of food under
14 this section—

15 “(A) whose purpose is to determine wheth-
16 er food is adulterated by reason of being con-
17 taminated with microorganisms, chemical tox-

1 ins, or pesticide chemicals or related residues;
2 and

3 “(B) whose results are available not later
4 than approximately 60 minutes after the ad-
5 ministration of the tests.

6 “(2) PRIORITY.—In providing for research
7 under paragraph (1), the Secretary shall give pri-
8 ority to conducting research on the development of
9 tests that are suitable for inspections of food at
10 ports of entry into the United States, with the great-
11 est priority given to the development of such tests
12 that the Secretary determines would be useful in de-
13 tecting the intentional adulteration of food. In pro-
14 viding for research under paragraph (1), the Sec-
15 retary shall under the preceding sentence give pri-
16 ority to conducting research on the development of
17 tests for detecting the presence in food of the patho-
18 gens *E. coli*, salmonella, cyclospora, cryptosporidium,
19 hepatitis A, or listeria, the presence in or on food of
20 pesticide chemicals and related residues, the pres-
21 ence in or on food of chemical toxins, and the pres-
22 ence in or on food of such other pathogens or sub-
23 stances as the Secretary determines to be appro-
24 priate, including any pathogen or substance that the
25 Secretary determines is a candidate for use to inten-

1 tionally adulterate food. The Secretary shall estab-
2 lish the goal of developing, by the expiration of the
3 3-year period beginning on the date of the enact-
4 ment of the this subsection, tests under paragraph
5 (1) for each of the pathogens and substances receiv-
6 ing priority under the preceding sentence.

7 “(3) PERIODIC REPORTS.—The Secretary shall
8 submit to the Congress periodic reports describing
9 the progress that has been made toward the goal re-
10 referred to in paragraph (1) and describing plans for
11 future research toward the goal. Each of the reports
12 shall provide an estimate by the Secretary of the
13 amount of funds needed to meet such goal, and shall
14 provide a determination by the Secretary of whether
15 there is a need for further research under this sub-
16 section. The first such report shall be submitted not
17 later than March 1, 2008, and subsequent reports
18 shall be submitted semiannually after the submission
19 of the first report until the goal is met.

20 “(4) CONSULTATION.—The Secretary shall
21 carry out the program of research under paragraph
22 (1) in consultation with the Director of the Centers
23 for Disease Control and Prevention, the Director of
24 the National Institutes of Health, and the Adminis-
25 trator of the Environmental Protection Agency. The

1 Secretary shall with respect to such research coordi-
2 nate the activities of the Department of Health and
3 Human Services. The Secretary shall in addition
4 consult with the Secretary of Agriculture (acting
5 through the Food Safety and Inspection Service of
6 the Department of Agriculture) in carrying out the
7 program.”.

8 **SEC. 3. USER FEES REGARDING INSPECTIONS OF IM-**
9 **PORTED FOOD SAFETY.**

10 Chapter VIII of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 381 et seq.) is amended by inserting
12 after section 801 the following:

13 “USER FEES REGARDING FOOD SAFETY

14 “SEC. 801A. (a) IN GENERAL.—

15 “(1) ASSESSMENT.—Beginning in fiscal year
16 2008, the Secretary shall in accordance with this
17 section assess and collect fees on food imported into
18 the United States.

19 “(2) PURPOSE OF FEES.—

20 “(A) IN GENERAL.—The purpose of fees
21 under paragraph (1) is to defray the costs of
22 carrying out section 801 with respect to food
23 over the costs of carrying out such section with
24 respect to food in fiscal year 2007 multiplied by
25 the adjustment factor. Fees under paragraph
26 (1) may be used to pay for overseas inspection

1 with respect to food by the Department of
2 Health and Human Services.

3 “(B) ALLOCATIONS BY SECRETARY.—Of
4 the total fee revenues collected under paragraph
5 (1) for a fiscal year, the Secretary shall reserve
6 and expend amounts in accordance with the fol-
7 lowing:

8 “(i) The Secretary shall reserve not
9 less than 90 percent for carrying out sec-
10 tion 801 with respect to food, other than
11 research under section 801(p). In expend-
12 ing the amount so reserved, the Secretary
13 shall give priority to inspections conducted
14 at ports of entry into the United States,
15 with the greatest priority given to inspec-
16 tions to detect the intentional adulteration
17 of food.

18 “(ii) The Secretary shall reserve not
19 more than 10 percent for carrying out re-
20 search under section 801(p).

21 “(C) LABORATORY TESTING.—In this
22 paragraph, the term ‘costs of carrying out sec-
23 tion 801’ with respect to food being imported or
24 offered for import includes the costs of labora-

1 tory testing of such food, including laboratory
2 personnel costs.

3 “(3) AMOUNT OF FEE; COLLECTION.—A fee
4 under paragraph (1) shall be assessed on each line
5 item of food, as defined by the Secretary by regula-
6 tion. The amount of the fee shall be based on the
7 number of line items, and may not exceed \$50 per
8 line item, notwithstanding subsection (b). The liabil-
9 ity for the fee constitutes a personal debt due to the
10 United States, and such liability accrues on the date
11 on which the Secretary approves the food under sec-
12 tion 801(c)(1). The Secretary may coordinate with
13 and seek the cooperation of other agencies of the
14 Federal Government regarding the collection of such
15 fees.

16 “(b) TOTAL FEE REVENUES.—The total fee revenues
17 collected under subsection (a) for a fiscal year shall be
18 the amount appropriated under subsection (f)(3).

19 “(c) ADJUSTMENTS.—

20 “(1) INFLATION ADJUSTMENT.—With respect
21 to the amount of total fee revenues referred to in
22 subsection (b), the amount authorized in subsection
23 (f)(3) for a fiscal year shall be adjusted by the Sec-
24 retary (and as adjusted shall be published in the
25 Federal Register) to reflect the greater of—

1 “(A) the total percentage change that oc-
2 curred during the preceding fiscal year in the
3 Consumer Price Index for all urban consumers
4 (all items; U.S. city average); or

5 “(B) the total percentage change for such
6 fiscal year in basic pay under the General
7 Schedule in accordance with section 5332 of
8 title 5, United States Code, as adjusted by any
9 locality-based comparability payment pursuant
10 to section 5304 of such title for Federal em-
11 ployees stationed in the District of Columbia.

12 “(2) ANNUAL FEE ADJUSTMENT.—Not later
13 than 60 days after the end of each fiscal year begin-
14 ning after fiscal year 2008, the Secretary, subject to
15 not exceeding the maximum fee amount specified in
16 subsection (a)(3), shall adjust the amounts that oth-
17 erwise would under subsection (a) be assessed as
18 fees during the fiscal year in which the adjustment
19 occurs so that the total revenues collected in such
20 fees for such fiscal year equal the amount applicable
21 pursuant to subsection (b) for the fiscal year.

22 “(d) FEE WAIVER OR REDUCTION.—The Secretary
23 shall grant a waiver from or a reduction of a fee assessed
24 under subsection (a) where the Secretary finds that the
25 fee to be paid will exceed the anticipated present and fu-

1 ture costs incurred by the Secretary in carrying out sec-
2 tion 801 with respect to food (which finding may be made
3 by the Secretary using standard costs).

4 “(e) ASSESSMENT OF FEES.—

5 “(1) LIMITATION.—Fees may not be assessed
6 under subsection (a) for a fiscal year beginning after
7 fiscal year 2008 unless the amount appropriated for
8 salaries and expenses of the Food and Drug Admin-
9 istration for such fiscal year is equal to or greater
10 than the amount appropriated for salaries and ex-
11 penses of the Food and Drug Administration for fis-
12 cal year 2008 multiplied by the adjustment factor
13 applicable to the fiscal year involved, except that in
14 making determinations under this paragraph for the
15 fiscal years involved there shall be excluded—

16 “(A) the amounts appropriated under sub-
17 section (f)(3) for the fiscal years involved;

18 “(B) the amounts appropriated under sec-
19 tion 801B(f)(3) for such fiscal years; and

20 “(C) the amounts appropriated under sec-
21 tion 736(g) for such fiscal years.

22 “(2) AUTHORITY.—If the Secretary does not
23 assess fees under subsection (a) during any portion
24 of a fiscal year because of paragraph (1) and if at
25 a later date in such fiscal year the Secretary may as-

1 sess such fees, the Secretary may assess and collect
2 such fees, without any modification in the rate of
3 the fees, at any time in such fiscal year notwith-
4 standing the provisions of subsection (a)(3) relating
5 to the time at which fees are to be paid.

6 “(f) CREDITING AND AVAILABILITY OF FEES.—

7 “(1) IN GENERAL.—Fees collected for a fiscal
8 year pursuant to subsection (a) shall be credited to
9 the appropriation account for salaries and expenses
10 of the Food and Drug Administration and shall be
11 available in accordance with appropriation Acts until
12 expended without fiscal year limitation. Such sums
13 as may be necessary may be transferred from the
14 Food and Drug Administration salaries and ex-
15 penses appropriation account without fiscal year lim-
16 itation to such appropriation account for salaries
17 and expenses with such fiscal year limitation. The
18 sums transferred shall be available solely for car-
19 rying out section 801 with respect to food, and the
20 sums are subject to allocations under subsection
21 (a)(2)(B).

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—The fees authorized in subsection (a)—

1 “(A) shall be collected in each fiscal year
2 in accordance with subsections (a)(3) and (b);
3 and

4 “(B) shall only be collected and available
5 for the purpose specified in subsection (a)(2).

6 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
7 LOCATIONS BY SECRETARY.—Subject to paragraph
8 (4) and subsection (c)(1), there is authorized to be
9 appropriated for fees under this section
10 \$500,000,000 for each of the fiscal years 2008
11 through 2012.

12 “(4) OFFSET.—Any amount of fees collected
13 for a fiscal year under subsection (a) that exceeds
14 the amount of fees specified in appropriation Acts
15 for such fiscal year shall be credited to the appro-
16 priation account of the Food and Drug Administra-
17 tion as provided in paragraph (1), and shall be sub-
18 tracted from the amount of fees that would other-
19 wise be authorized to be collected under this section
20 pursuant to appropriation Acts for a subsequent fis-
21 cal year.

22 “(g) COLLECTION OF UNPAID FEES.—In any case
23 where the Secretary does not receive payment of a fee as-
24 sessed under subsection (a) within 30 days after it is due,
25 such fee shall be treated as a claim of the United States

1 Government subject to subchapter II of chapter 37 of title
2 31, United States Code.

3 “(h) CONSTRUCTION.—This section may not be con-
4 strued as requiring that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employees, and advisory committees not
7 engaged in carrying out section 801 with respect to food
8 be reduced to offset the number of officers, employees, and
9 advisory committees so engaged.

10 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
11 purposes of this section, the term ‘adjustment factor’ ap-
12 plicable to a fiscal year is the Consumer Price Index for
13 all urban consumers (all items; United States city average)
14 for April of the preceding fiscal year divided by such Index
15 for April 2007.”.

16 **SEC. 4. USER FEES REGARDING INSPECTIONS OF IM-**
17 **PORTED DRUG SAFETY.**

18 Chapter VIII of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 381 et seq.), as amended by section
20 3, is further amended by inserting after section 801A the
21 following:

22 “USER FEES REGARDING DRUG SAFETY

23 “SEC. 801B. (a) IN GENERAL.—

24 “(1) ASSESSMENT.—Beginning in fiscal year
25 2008, the Secretary shall in accordance with this

1 section assess and collect fees on drugs imported
2 into the United States.

3 “(2) PURPOSE OF FEES.—

4 “(A) IN GENERAL.—The purpose of fees
5 under paragraph (1) is to defray the costs of
6 carrying out section 801 with respect to drugs
7 over the costs of carrying out such section with
8 respect to drugs in fiscal year 2007 multiplied
9 by the adjustment factor. Fees under paragraph
10 (1) may be used to pay for overseas inspection
11 with respect to drugs by the Department of
12 Health and Human Services.

13 “(B) PRIORITY.—In expending the fee rev-
14 enue amounts collected under paragraph (1),
15 the Secretary shall give priority to—

16 “(i) inspections conducted at ports of
17 entry into the United States, with the
18 greatest priority given to inspections to de-
19 tect the intentional adulteration or mis-
20 branding of drugs; and

21 “(ii) inspections of good manufac-
22 turing practices conducted abroad.

23 “(C) LABORATORY TESTING.—In this
24 paragraph, the term ‘costs of carrying out sec-
25 tion 801’ with respect to drugs being imported

1 or offered for import includes the costs of lab-
2 oratory testing of such drugs, including labora-
3 tory personnel costs.

4 “(3) AMOUNT OF FEE; COLLECTION.—A fee
5 under paragraph (1) shall be assessed on each line
6 item of drugs, as defined by the Secretary by regula-
7 tion. The amount of the fee shall be based on the
8 number of line items, and may not exceed \$1000 per
9 line item, notwithstanding subsection (b). The liabil-
10 ity for the fee constitutes a personal debt due to the
11 United States, and such liability accrues on the date
12 on which the Secretary approves the drugs under
13 section 801(c)(1). The Secretary may coordinate
14 with and seek the cooperation of other agencies of
15 the Federal Government regarding the collection of
16 such fees.

17 “(b) TOTAL FEE REVENUES.—The total fee revenues
18 collected under subsection (a) for a fiscal year shall be
19 the amount appropriated under subsection (f)(3).

20 “(c) ADJUSTMENTS.—

21 “(1) INFLATION ADJUSTMENT.—With respect
22 to the amount of total fee revenues referred to in
23 subsection (b), the amount authorized in subsection
24 (f)(3) for a fiscal year shall be adjusted by the Sec-

1 retary (and as adjusted shall be published in the
2 Federal Register) to reflect the greater of—

3 “(A) the total percentage change that oc-
4 curred during the preceding fiscal year in the
5 Consumer Price Index for all urban consumers
6 (all items; U.S. city average); or

7 “(B) the total percentage change for such
8 fiscal year in basic pay under the General
9 Schedule in accordance with section 5332 of
10 title 5, United States Code, as adjusted by any
11 locality-based comparability payment pursuant
12 to section 5304 of such title for Federal em-
13 ployees stationed in the District of Columbia.

14 “(2) ANNUAL FEE ADJUSTMENT.—Not later
15 than 60 days after the end of each fiscal year begin-
16 ning after fiscal year 2008, the Secretary, subject to
17 not exceeding the maximum fee amount specified in
18 subsection (a)(3), shall adjust the amounts that oth-
19 erwise would under subsection (a) be assessed as
20 fees during the fiscal year in which the adjustment
21 occurs so that the total revenues collected in such
22 fees for such fiscal year equal the amount applicable
23 pursuant to subsection (b) for the fiscal year.

24 “(d) FEE WAIVER OR REDUCTION.—The Secretary
25 shall grant a waiver from or a reduction of a fee assessed

1 under subsection (a) where the Secretary finds that the
2 fee to be paid will exceed the anticipated present and fu-
3 ture costs incurred by the Secretary in carrying out sec-
4 tion 801 with respect to drugs (which finding may be
5 made by the Secretary using standard costs).

6 “(e) ASSESSMENT OF FEES.—

7 “(1) LIMITATION.—Fees may not be assessed
8 under subsection (a) for a fiscal year beginning after
9 fiscal year 2008 unless the amount appropriated for
10 salaries and expenses of the Food and Drug Admin-
11 istration for such fiscal year is equal to or greater
12 than the amount appropriated for salaries and ex-
13 penses of the Food and Drug Administration for fis-
14 cal year 2008 multiplied by the adjustment factor
15 applicable to the fiscal year involved, except that in
16 making determinations under this paragraph for the
17 fiscal years involved there shall be excluded—

18 “(A) the amounts appropriated under sub-
19 section (f)(3) for the fiscal years involved;

20 “(B) the amounts appropriated under sec-
21 tion 801A(f)(3) for such fiscal years; and

22 “(C) the amounts appropriated under sec-
23 tion 736(g) for such fiscal years.

24 “(2) AUTHORITY.—If the Secretary does not
25 assess fees under subsection (a) during any portion

1 of a fiscal year because of paragraph (1) and if at
2 a later date in such fiscal year the Secretary may as-
3 sess such fees, the Secretary may assess and collect
4 such fees, without any modification in the rate of
5 the fees, at any time in such fiscal year notwith-
6 standing the provisions of subsection (a)(3) relating
7 to the time at which fees are to be paid.

8 “(f) CREDITING AND AVAILABILITY OF FEES.—

9 “(1) IN GENERAL.—Fees collected for a fiscal
10 year pursuant to subsection (a) shall be credited to
11 the appropriation account for salaries and expenses
12 of the Food and Drug Administration and shall be
13 available in accordance with appropriation Acts until
14 expended without fiscal year limitation. Such sums
15 as may be necessary may be transferred from the
16 Food and Drug Administration salaries and ex-
17 penses appropriation account without fiscal year lim-
18 itation to such appropriation account for salaries
19 and expenses with such fiscal year limitation. The
20 sums transferred shall be available solely for car-
21 rying out section 801 with respect to drugs.

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—The fees authorized in subsection (a)—

1 “(A) shall be collected in each fiscal year
2 in accordance with subsections (a)(3) and (b);
3 and

4 “(B) shall only be collected and available
5 for the purpose specified in subsection (a)(2).

6 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
7 LOCATIONS BY SECRETARY.—Subject to paragraph
8 (4) and subsection (c)(1), there is authorized to be
9 appropriated for fees under this section
10 \$300,000,000 for each of the fiscal years 2008
11 through 2012.

12 “(4) OFFSET.—Any amount of fees collected
13 for a fiscal year under subsection (a) that exceeds
14 the amount of fees specified in appropriation Acts
15 for such fiscal year shall be credited to the appro-
16 priation account of the Food and Drug Administra-
17 tion as provided in paragraph (1), and shall be sub-
18 tracted from the amount of fees that would other-
19 wise be authorized to be collected under this section
20 pursuant to appropriation Acts for a subsequent fis-
21 cal year.

22 “(g) COLLECTION OF UNPAID FEES.—In any case
23 where the Secretary does not receive payment of a fee as-
24 sessed under subsection (a) within 30 days after it is due,
25 such fee shall be treated as a claim of the United States

1 Government subject to subchapter II of chapter 37 of title
2 31, United States Code.

3 “(h) CONSTRUCTION.—This section may not be con-
4 strued as requiring that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employees, and advisory committees not
7 engaged in carrying out section 801 with respect to drugs
8 be reduced to offset the number of officers, employees, and
9 advisory committees so engaged.

10 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
11 purposes of this section, the term ‘adjustment factor’ ap-
12 plicable to a fiscal year is the Consumer Price Index for
13 all urban consumers (all items; United States city average)
14 for April of the preceding fiscal year divided by such Index
15 for April 2007.”.

16 **SEC. 5. AUTHORITY TO RESTRICT FOOD IMPORTATION TO**
17 **SPECIFIC PORTS OF ENTRY.**

18 Section 801 of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 381), as amended by section 2, is further
20 amended by adding at the end the following:

21 “(q) AUTHORITY TO RESTRICT FOOD IMPORTATION
22 TO SPECIFIC PORTS OF ENTRY.—

23 “(1) IN GENERAL.—The Secretary shall restrict
24 the importation of all food to ports of entry that are
25 located in a metropolitan area with a laboratory of

1 the Food and Drug Administration for testing such
2 food.

3 “(2) WAIVER.—The Secretary may waive the
4 requirement of paragraph (1) and authorize the im-
5 portation of food to a port of entry not described in
6 such paragraph if the Secretary certifies that—

7 “(A) the importation of such food through
8 such port will not increase the probability that
9 such food will cause serious, adverse health con-
10 sequences or death; or

11 “(B) there is a reasonable probability that
12 the type food involved will not cause serious,
13 adverse health consequences or death.

14 “(3) IMPLEMENTATION.—The Secretary shall
15 implement this subsection beginning not later than
16 5 years after the date of the enactment of this sub-
17 section.”.

18 **SEC. 6. COUNTRY OF ORIGIN LABELING.**

19 (a) FOOD.—Section 403 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 343) is amended by adding
21 at the end the following:

22 “(z) If the labeling of the food fails to identify the
23 country of origin of the food.”.

1 (b) DRUGS AND DEVICES.—Section 502 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
3 amended by adding at the end the following:

4 “(y) If it is a drug or device and its labeling fails
5 to identify the country of origin of the drug or device.”.

6 (c) REGULATIONS.—Not later than 180 days after
7 the date of the enactment of this Act, the Secretary shall
8 promulgate final regulations to carry out sections 403(z)
9 and 502(y) of the Federal Food, Drug, and Cosmetic Act,
10 as added by subsections (a) and (b), respectively.

11 (d) EFFECTIVE DATE.—The requirements of sections
12 403(z) and 502(y) of the Federal Food, Drug, and Cos-
13 metic Act, as added by subsections (a) and (b), respec-
14 tively, take effect on the date that is 180 days after the
15 date of the enactment of this Act.

16 **SEC. 7. SAFE AND SECURE FOOD IMPORTATION PROGRAM.**

17 Chapter VIII of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 381 et seq.) is amended by adding
19 at the end the following:

20 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
21 **GRAM.**

22 “(a) IN GENERAL.—Beginning not later than 2 years
23 after the date of the enactment of this section, the Sec-
24 retary shall establish by regulation and carry out a pro-
25 gram under which—

1 “(1) persons importing food into the United
2 States voluntarily agree to abide by the food safety
3 and security guidelines developed under subsection
4 (b); and

5 “(2) the Secretary agrees to expedite the move-
6 ment of such food through the inspection process.

7 “(b) GUIDELINES.—

8 “(1) DEVELOPMENT.—For purposes of the pro-
9 gram established under subsection (a), the Secretary
10 shall develop safety and security guidelines applica-
11 ble to the importation of food.

12 “(2) FACTORS.—The guidelines developed
13 under paragraph (1) shall take into account the fol-
14 lowing factors:

15 “(A) The personnel of the person import-
16 ing the food.

17 “(B) The physical and procedural safety
18 and security of such person’s food supply chain.

19 “(C) The sufficiency of access controls for
20 food and ingredients purchased by such person.

21 “(D) The need for tracking and maintain-
22 ing records on food and ingredients purchased
23 by such person or moved through the supply
24 chain.

1 “(E) Documentation processing through
2 such person’s supply chain.

3 “(F) Access by the Secretary to such per-
4 son’s business records for review.

5 “(G) Vendor and supplier information.

6 “(H) Such other factors as the Secretary
7 determines necessary.”.

8 **SEC. 8. CIVIL PENALTIES.**

9 Section 303 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C.333) is amended—

11 (1) by redesignating subsection (g) (relating to
12 civil penalties) as subsection (f); and

13 (2) in subparagraph (A) of paragraph (2) of
14 subsection (f), as so redesignated, by striking “Any
15 person who introduces” and all that follows through
16 the end of the subparagraph and inserting the fol-
17 lowing: “Any person who introduces into interstate
18 commerce or delivers for introduction into interstate
19 commerce an article of food that is adulterated with-
20 in the meaning of section 402(a)(2)(B) shall be sub-
21 ject to a civil money penalty of—

22 “(i) not more than \$50,000 in the case of any
23 individual and \$250,000 in the case of any other
24 person for such introduction or delivery, not to ex-

1 ceed \$500,000 for all such violations adjudicated in
2 a single proceeding; or

3 “(ii) notwithstanding clause (i), if such person
4 is the manufacturer or the importer of the food, not
5 more than \$100,000 in the case of any individual
6 and \$500,000 in the case of any other person for
7 such introduction or delivery, not to exceed
8 \$1,000,000 for all such violations adjudicated in a
9 single proceeding.”.

10 **SEC. 9. CONTINUED OPERATION OF FIELD LABORATORIES.**

11 (a) IN GENERAL.—Subject to subsections (b) and
12 (d), the Secretary of Health and Human Services (in this
13 section referred to as the “Secretary”) shall not—

14 (1) terminate any of the 13 field laboratories
15 that were operated by the Office of Regulatory Af-
16 fairs of the Food and Drug Administration as of
17 January 1, 2007;

18 (2) consolidate any such laboratory with any
19 other laboratory;

20 (3) terminate any of the 20 district offices or
21 any of the inspection or compliance functions of any
22 of the 20 district offices of the Food and Drug Ad-
23 ministration functioning as of January 1, 2007; or

24 (4) consolidate—

1 (A) any such district office with an office
2 in any other district; or

3 (B) transfer any of the compliance or in-
4 spection functions of any such district office to
5 any other district.

6 (b) REPORT BY SECRETARY.—

7 (1) SUBMISSION.—The Secretary shall submit a
8 reorganization plan involving the termination or con-
9 solidation of the laboratories, the district offices, or
10 the functions of such district offices specified in sub-
11 section (a) to the Comptroller General, the Com-
12 mittee on Energy and Commerce of the House of
13 Representatives, and the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate.

15 (2) CONSULTATION.—In preparing the reorga-
16 nization plan described in paragraph (1), the Sec-
17 retary shall consult with personnel and unions to be
18 affected by the plan.

19 (c) REPORT BY GAO.—The Comptroller General
20 shall study the cost effectiveness of the reorganization
21 plan described in subsection (b) and its impact on the
22 safety of food, drug, and other products regulated under
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
24 et seq.) and the Public Health Service Act (42 U.S.C. 201
25 et seq.) and report to the Committee on Energy and Com-

1 merce of the House of Representatives and the Committee
2 on Health, Education, Labor, and Pensions of the Senate.

3 (d) REORGANIZATION.—

4 (1) CONGRESSIONAL REVIEW.—The reorganiza-
5 tion plan described in subsection (b) is deemed to be
6 a major rule (as defined in section 804(2) of title 5,
7 United States Code) for purposes of chapter 8 of
8 such title.

9 (2) EFFECTIVE DATE.—Notwithstanding sec-
10 tion 801(a)(3) of title 5, United States Code, the re-
11 organization plan described in subsection (b) shall
12 take effect (unless disapproved under section 802 of
13 such title) on the date that is 180 days after the
14 date on which the Comptroller General submits the
15 report required by subsection (c).

16 **SEC. 10. RECALL AUTHORITY.**

17 Chapter IV of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 351 et seq.), as amended by section 6 of
19 this Act, is amended by adding at the end the following:

20 **“SEC. 418. RECALL AUTHORITY.**

21 **“(a) ORDER TO CEASE DISTRIBUTION.—**

22 **“(1) IN GENERAL.—**If the Secretary finds that
23 a food may cause serious, adverse health con-
24 sequences or death, the Secretary shall issue an
25 order requiring the appropriate person (including

1 the manufacturers, importers, distributors, or retail-
2 ers of the food) to immediately cease distribution of
3 the food.

4 “(2) INFORMAL HEARING.—An order under
5 paragraph (1) shall provide the person subject to the
6 order with an opportunity for an informal hearing,
7 to be held not later than 10 days after the date of
8 the issuance of the order, on the actions required by
9 the order and on whether the order should be
10 amended to require a recall of the food involved. If,
11 after providing an opportunity for such a hearing,
12 the Secretary determines that inadequate grounds
13 exist to support the actions required by the order,
14 the Secretary shall vacate the order.

15 “(b) ORDER TO RECALL.—

16 “(1) IN GENERAL.—If, after providing an op-
17 portunity for an informal hearing under subsection
18 (a)(2), the Secretary determines that the order
19 should be amended to include a recall of the food
20 with respect to which the order was issued, the Sec-
21 retary shall, except as provided in paragraphs (2)
22 and (3), amend the order to require a recall. The
23 Secretary shall specify a timetable in which the food
24 recall will occur and shall require periodic reports to
25 the Secretary describing the progress of the recall.

1 “(2) CERTAIN ACTIONS.—An amended order
2 under paragraph (1) shall not include recall of a
3 food from individuals.”.

4 **SEC. 11. INSPECTION AND OTHER STANDARDS; APPLICA-**
5 **BILITY, ENFORCEMENT; CERTIFICATIONS.**

6 Chapter IV of the Federal Food, Drug, and Cosmetic
7 Act, as amended by section 10 of this Act, is amended
8 by adding at the end the following:

9 **“SEC. 419. INSPECTION AND OTHER STANDARDS; APPLICA-**
10 **BILITY, ENFORCEMENT; CERTIFICATIONS.**

11 “(a) IN GENERAL.—Notwithstanding any other pro-
12 vision of law, all food that is offered for importation into
13 the United States shall be subject to the food safety stand-
14 ards applied to such food produced in the United States.

15 “(b) ENFORCEMENT.—Any food that appears to not
16 meet all the standards referred to in subsection (a) shall
17 be considered adulterated and shall not be permitted entry
18 into the United States.

19 “(c) RANDOM INSPECTIONS.—The Secretary shall
20 enforce this section through appropriate random inspec-
21 tions, sampling, and testing.

22 “(d) CERTIFICATIONS REGARDING FOREIGN FACILI-
23 TIES.—

1 “(1) REQUIREMENT.—No food shall be per-
2 mitted entry into the United States from a foreign
3 facility in a foreign country unless there is—

4 “(A) a certification for such facility in ef-
5 fect under paragraph (2)(A); or

6 “(B) a certification for such country under
7 paragraph (2)(B).

8 “(2) CERTIFICATION.—

9 “(A) FOREIGN FACILITY.—Each foreign
10 facility seeking to import food into the United
11 States may obtain a certification by the Sec-
12 retary stating that the facility maintains a pro-
13 gram using reliable analytical methods to en-
14 sure compliance with all the standards referred
15 to in subsection (a).

16 “(B) FOREIGN COUNTRY.—A foreign coun-
17 try may obtain a certification by the Secretary
18 stating that—

19 “(i) the country has in effect and is
20 enforcing food safety standards at least as
21 protective of food safety as the standards
22 applicable to food in the United States;
23 and

24 “(ii) the country has a program in ef-
25 fect to monitor and enforce its food safety

1 standards with respect to food being ex-
2 ported from such country to the United
3 States.

4 “(3) PERIODIC REVIEW.—The Secretary shall
5 periodically review certifications under paragraph (2)
6 and shall revoke any certification if the Secretary
7 determines that the foreign facility or foreign coun-
8 try involved is no longer meeting the requirements
9 described in such paragraph.

10 “(4) INSPECTION.—The consideration of any
11 application for a certification under paragraph (2)
12 and the review of any such certification, by the Sec-
13 retary, may include the inspection of foreign facili-
14 ties to ensure that the inspection program of the for-
15 eign facility involved is meeting such standards.

16 “(5) FOREIGN FACILITY.—In this subsection,
17 the term ‘foreign facility’ means a foreign facility (as
18 defined in section 415(b)(3)) that is required to be
19 registered under section 415.

20 “(6) EFFECTIVE DATE.—This subsection takes
21 effect beginning on the date that is 5 years after the
22 date of the enactment of the Food and Drug Import
23 Safety Act of 2007.”.

1 **SEC. 12. REGULATIONS ON ADEQUATE TESTING OF PROC-**
2 **ESSED FOOD.**

3 Chapter IV of the Federal Food, Drug, and Cosmetic
4 Act, as amended by section 11 of this Act, is amended
5 by adding at the end the following:

6 **“SEC. 420. REGULATIONS ON ADEQUATE TESTING OF PROC-**
7 **ESSED FOOD.**

8 “(a) IN GENERAL.—Not later than 2 years after the
9 date of the enactment of the Food and Drug Import Safe-
10 ty Act of 2007, the Secretary shall by regulation require
11 that, as good manufacturing practices, processed food un-
12 dergo testing to detect substances in the food that may
13 render the food adulterated, including microbial patho-
14 gens, toxic chemicals, and such other substances as the
15 Secretary determines to be appropriate.

16 “(b) REVIEW OF TEST RESULTS.—Regulations
17 under subsection (a) shall require that the results of tests
18 under such subsection be provided to the Secretary upon
19 demand.”.

20 **SEC. 13. RECORDS OF INTERSTATE SHIPMENT.**

21 Subsection (a) of section 703 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

23 (1) by striking “upon the request” and insert-
24 ing “upon the written or oral request”; and

25 (2) by striking “, except that evidence obtained
26 under this section, or any evidence which is directly

1 or indirectly derived from such evidence, shall not be
2 used in a criminal prosecution of the person from
3 whom obtained, and except that carriers shall not be
4 subject to the other provisions of this Act by reason
5 of their receipt, carriage, holding, or delivery of food,
6 drugs, devices, or cosmetics in the usual course of
7 business as carriers, except as provided in subsection
8 (b)’’.

9 **SEC. 14. LABELING REQUIREMENT FOR MEAT, POULTRY**
10 **PRODUCTS, AND SEAFOOD THAT CONTAIN**
11 **CARBON MONOXIDE.**

12 (a) LABELING REQUIREMENT.—

13 (1) IN GENERAL.—Paragraph (t) of section 201
14 of the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 321(t)) is amended by adding at the end the
16 following new paragraph:

17 “(4) In the case of food that is meat within the
18 meaning of the Federal Meat Inspection Act, a poul-
19 try product within the meaning of the Poultry Prod-
20 ucts Inspection Act, or seafood (including all fresh
21 or saltwater finfish, molluscan shellfish, crustaceans,
22 and other forms of aquatic animal life) intended for
23 human consumption as food within the meaning of
24 section 201(f) of this Act (referred to collectively in
25 this subsection as ‘seafood’), the term ‘color addi-

1 tive’ shall include carbon monoxide under conditions
2 of use that may impart, maintain, preserve, stabilize,
3 fix, or otherwise affect the color of fresh meat, poul-
4 try products, or seafood, unless the label of such
5 food bears, prominently and conspicuously in such
6 place and in such manner as to render it likely to
7 be read and understood by the ordinary person, the
8 following statement to prevent consumer deception
9 and serious risks to the public health: ‘SAFETY
10 NOTICE: Carbon monoxide has been used to pre-
11 serve the color of this product. Do not rely on color
12 or the “use or freeze by” date alone to judge the
13 freshness or safety of the product. Discard any prod-
14 uct with an unpleasant odor, slime, or a bulging
15 package.’”.

16 (2) EFFECTIVE DATE.—The amendment made
17 by this subsection shall apply to food labeled on or
18 after the date that is 30 days after the date of the
19 enactment of this Act.

20 (b) DISCRETIONARY AUTHORITY.—If, not earlier
21 than 5 years after the effective date described in sub-
22 section (a)(1), the Secretary of Health and Human Serv-
23 ices finds, based on competent and reliable scientific evi-
24 dence, that the statement prescribed in section 201(t)(4)
25 of the Federal Food, Drug, and Cosmetic Act is no longer

1 required to prevent consumer deception and other harms,
2 then the Secretary is authorized to issue regulations estab-
3 lishing alternative labeling requirements that are shown
4 to be adequate and effective in preventing consumer de-
5 ception and other harms related to the conditions of use
6 of carbon monoxide, including with respect to preventing
7 any consumer deception or other harm that may result
8 from the actual conditions of carbon monoxide use and
9 its potential to impart a persistent color to meat, poultry
10 products, or seafood described in such section through a
11 reaction with natural pigment.